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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,717	07/25/2003	Scott E. Andersen	38-21(15878)D	2211

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,717	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-8 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to the specification is withdrawn in view of the fact that the hyperlinks in the specification are not active.

4. The amendment to claims 1, and 4-6 to recite 'the complements thereof" have rendered the rejections under 35 USC 102, moot. Claims 1-5 are drawn to a sequence comprising or consisting of SEQ ID NO: 11, the complement thereof, or a sequence having between 90% an 100% identity *with* SEQ ID NO: 11, accordingly, the amended claims do not encompass sequences which are less than 392 nucleotides in length. Claim 6 is directed to a molecule that comprises a fragment from about 50-100 nucleotide residues wherein the fragment exhibits complete complementarity to SEQ ID NO: 11, and the complement thereof, accordingly, claims 6-8 do not encompass molecules which are less than 50 nucleotides long.

Claim Rejections - 35 USC § 101

5. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a substantially purified nucleic acid molecule comprising a sequence having between 90%, 95% and 100% sequence identity with SEQ ID NO: 11 (claims 1-4) as well as consisting of SEQ ID NO: 11 (claim 5). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) or consisting (claim 7) of a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, the complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claims 3 and 5 do not allow for internal variations within SEQ ID NO: 11. Claim 3 encompasses putative genes, full open reading frames, fusion constructs and cDNAs. Claims 1-2, 4, 6, and 8 allow for internal variations. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of these genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches that the claimed nucleic acid is an EST isolated from a wheat cDNA library. The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any EST. The specification discloses many potential uses for the polynucleotide including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32). These are non-

specific uses that are applicable to in general to polynucleotides isolated from wheat and not particular or specific to the polynucleotide claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. For example, the specification teaches that the claimed nucleic acids can be used to identify a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 11. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. The specification provides no indication as to what the nucleic acids are markers for. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 11 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 11 may only be used to search for polymorphisms and if such polymorphisms are identified then

the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 11 or a protein encoded by SEQ ID NO: 11. SEQ ID NO: 11 may be a portion of a full length open reading frame, but the specification does not teach which protein is actually encoded by SEQ ID NO: 11. For example, it is not clear if nucleotide number 1 is the first nucleotide in a codon, or the last. The specification does not teach an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids.

Likewise, none of the potential promoters, flanking sequences, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, flanking sequences, mutations, and genes does not constitute a specific and substantial utility.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or

suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) and *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). In *Brenner v. Manson*, the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In Fisher, the court held that Fisher's asserted uses for ESTs did not qualify as either specific or substantial utilities under *Brenner v. Manson*.

Claim Rejections - 35 USC § 112

6. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

7. The response traverses the rejections under 35 USC 101 and 112/first paragraph enablement for the same reasons. The response asserts that one use of the elected SEQ ID NO: 11 can be shown by a BLASTN analysis, which is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences and cites the specification at page 5,

lines 19-28. This argument has been thoroughly reviewed but was not found persuasive. Although the specification at page 5, explains how a BLASTN search is performed, the specification provides no specific or substantial utility for SEQ ID NO: 11. Any nucleic acid sequence, including any sequence from a wheat plant, can be used in a BLAST analysis. Such use in therefore not specific. This utility is not substantial because no substantial utility is set forth in the specification regarding any particular sequence obtained using BLAST analysis with SEQ ID NO: 11, nor what the specific and substantial utility of that sequence would be. The specification merely discloses that the skilled artisan may perform a BLASTN search on the sequences disclosed to then determine if a specific and substantial utility exist for the sequences in the specification. This is not a specific and substantial utility but rather an invitation for the artisan to then determine whether a specific and substantial utility exists. In the instant situation, the response references a search which showed 99% identity to a storage protein sequence obtained from Triticum aestivum and asserts that the sequence was obtained by Kawaura et al; Plant Physiol, vol. 139, pages 1870-1880, 2005. It is noted, however, that no alignment is provided nor does the response provide what database this alignment is obtained from, nor which sequence from Kawaura this corresponds to. Additionally, it is noted that SEQ ID NO: 11 is 392 nucleotides long, however the search indicates a score of identities of 259 out of 260. Accordingly it appears that the asserted 99% is only to a portion of SEQ ID NO: 11, whereas the amended claims recite, for example "between 90% and 100% sequence identity **with**... SEQ ID NO: 11", not to a portion of SEQ ID NO: 11. Further, the response fails to provide what portion of SEQ ID NO: 11 was responsible for this observed identity, nor does the specification provide any guidance whatsoever as to which portions from within SEQ ID NO: 11 should be searched,

again leaving it to the artisan to determine for themselves, what information may be gleaned from the disclosed sequence.

Regardless of such, however, it is noted that the instant application effective priority date is 6/15/2000 and the filing date of the instant application is 7/25/2003, while the paper cited was published in 2005. The specification at the time the invention was filed only generally discloses that the SEQ ID NOS can have high homology to wheat proteins but does not teach what these wheat proteins are, how they function, or whether any homology less than 100% identity would provide for a predictable correlation between the structure and function of the putative unknown, undisclosed homologue. However, In *Brenner v. Manson*, the court held that : "...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion." Here, the specification does not teach homology to storage proteins, nor what the utility of a storage protein is or whether all storage proteins have the same structure and function or whether less than 100% identity to a storage protein would predictably determine what the specific function of that protein was. The reference cited in the response was published after the instant invention was filed and does not provide for a well established utility for SEQ ID NO: 11 at the time of the invention. The response's assertion with regard to "reasonable correlation" has been thoroughly reviewed but was not found persuasive. In *Fujikawa v. Wattanasin*, the issue referenced in the response related to reasonable correlation between in vitro and in vivo pharmacological activity of a compound. However, in the instant application, the specification fails to disclose any in vitro or in vivo activity for SEQ ID NO: 11 or a protein, if one exists, encoded by SEQ ID NO: 11. The argument that that BLASTN analysis provides reasonable correlation is not found persuasive. It is not clear or apparent what reasonable correlation is

determined from 99% identity over only a portion of SEQ ID NO: 11 (66%) with a sequence determined after the filing date of the instant application, nor is such taught in the specification.

The rejection is maintained.

8. Claims 1-4, 6, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a substantially purified nucleic acid molecule comprising a sequence having between 90%, 95% and 100% sequence identity with SEQ ID NO: 11 (claims 1-4). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) a fragment of about 50 to about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claim 3 does not allow for internal variations within SEQ ID NO: 11. However, SEQ ID NO: 11 does not appear to be a full length open reading frame and therefore, claim 3 encompasses putative genes, full open reading frames, fusion constructs and cDNAs. Claims 1-2, 4, 6 and 8 allow for internal variations within SEQ ID NO: 11. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of these genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches the sequence of SEQ ID NO: 11. SEQ ID NO: 11, per se, meets the written description requirement of 35 USC 112, first paragraph. However, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library. However, the specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first nucleotide in a codon, or the second or third. Accordingly, it is not even clear that SEQ ID NO: 11 encodes a protein (claim 2). Further, claim 2 specifically recites a nucleic acid which encodes a wheat protein, or fragment of a wheat protein. However, the specification does not teach what structural requirements of the genus of nucleic acids of claim 1 make a sequence a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of SEQ ID NO: 11, distinguish it from "non wheat" proteins. Accordingly, it is not representative of the genus of sequences encompassed by the claims. Further, claims 1, 2, 4, 6, and 8 encompass sequences which possess variations with regard to the sequence of SEQ ID NO: 1, while claims 1-4, 6, and 8, due to the language "comprising" encompass a large genus of sequences which are larger than SEQ ID NO: 11. Although, for example, claim 3 encompasses a vector which comprises SEQ ID NO: 11, the claim also encompasses a full length cDNA, as well as genomic sequences, which have not been described by the specification. Such sequences include introns, exons, promoters, enhancers, 5' and 3' UTR's, all of which have not been described by the specification. Further, claims 1, 2, 4, 6, and 8 encompass allelic variants, mutants, and homologs

of the undisclosed cDNA and genomic sequences. As such, each member of the claimed genus does not contain the same structural feature. This represent a large variable genus of nucleic acid molecules which are not represented by the single sequence of SEQ ID NO: 11. The specification does not disclose a single variant or homolog of SEQ ID NO: 11, nor any sequence with a "single nucleotide polymorphism". There is no structure function correlation between the single disclosed species, and the large genus of genes, cDNAs, mutants, variants, and homologs encompassed by the broadly claimed invention.

Beyond providing the sequence data for SEQ ID NO: 11, however, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO: 11 to its function, which amino acids in the protein encoded by SEQ ID NO: 11 are critical to its function, or how to modify SEQ ID NO: 11 to obtain any specific homolog, mutant, or variant. It is not clear which positions with SEQ ID NO: 11 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 11. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 11.

While one could argue that the claimed genus of polynucleotides is adequately described since one can identify these polynucleotides by sequence comparison using the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone is not a reliable indicator of a protein's function. For example, Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate,

and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

The genus of polynucleotides comprised by the claims is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 11, which is insufficient to put one of skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 1-4, 6, and 8.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of a substantially purified nucleic acid molecule consisting of the sequence of SEQ ID NO: 11, and the complete complement thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for

isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to arguments

9. The response traverses the rejection. The response asserts that that the specification demonstrates that applicant was in possession of the claimed genus of nucleic acid molecules when the application was filed and that the applicants have provided a detailed chemical structure of SEQ ID NO: 11. It is further asserted that the fact that the claims are joined with additional sequences, or variants is beside the point because such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. complements of the recited sequence or nucleic aid molecules that share a claimed identity with

This argument was thoroughly reviewed but was not found persuasive. The rejection is based on the fact that the claims include full length genomic sequences comprising the recited SEQ ID NO: 11 (claim 3) or a fragment of SEQ ID NO: 11 (claim 6). With regard to claim 2, the specification provides no description as to attributes which would make a sequence as claimed in claim 11, encode a wheat protein, as opposed to any protein in general. With regard to claims 1 and 4, the claims further encompass sequences having between 90% to 100% identity with SEQ ID NO: 11 and sequences comprising these variant sequences. With regard to claim 8, the claim further encompasses sequences which are polymorphic with respect to SEQ ID NO: 11. Thereby, the claims encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 11 which are not adequately described in the present specification. The genus of nucleic acids encompassed by the claims is extremely broad and is not limited to vectors comprising the nucleic acids or to nucleic acids comprising a label. The claims further encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 11. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids. As discussed in the rejection, the court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While the specification is not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of

DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, the specification has provided only a disclosure of a wish to obtain homologues, mutant, allelic, and splice variants of SEQ ID NO: 11. The specification does not disclose any specific mutant, allelic, or splice variants or homologues or SPSs of SEQ ID NO: 11. Further, the functional activity of such variants is not disclosed. Accordingly, the specification has not disclosed a representative number of nucleic acid molecules within the claimed genus.

Although the response asserts that applicants have provided a detailed chemical structure, SEQ ID NO: 11, the claims are not limited to nucleic acids which share this common structural feature. Rather, the claims encompass nucleic acids having between 90 and 100% identity with SEQ ID NO: 11. Thereby, the claimed genus of nucleic acids do not share the same common structural feature of containing the sequence of SEQ ID NO: 11. The specification does not disclose what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature. The genus of molecules having 90-99.9% identity with SEQ ID NO: 11 includes individual species of nucleic acids which may vary from SEQ ID NO: 11 at any given nucleotide position within SEQ ID NO: 11. When the individual species within the genus are compared to one another, together this genus comprises nucleic acids which vary at each and every nucleotide position within SEQ ID NO: 11. Accordingly, the genus of nucleic acids are not considered to share a common structural feature – i.e., there is no specific structural property that is common to all members of the claimed genus if each of the individual nucleotides may be varied. Further, the claims do not

recite a functional requirement for any of the claimed nucleic acids and thereby encompass nucleic acids having distinct functional properties.

The response asserts that nucleic acids falling within the scope of the claims are readily identifiable and that one of ordinary skill in the art could identify whether a particular sequence meets the claimed characteristics or not. However, it is noted that the criteria for meeting the Written Description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the Written Description requirement is met by providing a showing that Applicants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 90-99.9% identity with SEQ ID NO: 11 is not equivalent to disclosing specific nucleic acids which fall within the claimed genus of nucleic acids. The specification does not disclose a single molecule within the genus of nucleic acids having 90-99.9% identity with SEQ ID NO: 11. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 11, and does not describe the functional activity or other biological role associated with such variants. The specification also does not disclose any specific variants of SEQ ID NO: 11 which have a functional activity or biological role distinct from that of SEQ ID NO: 11. Modification of a nucleic acid sequence by 1 to 10% can significantly alter the functional activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of this genus, i.e., SEQ ID NO: 11. This is not sufficient to place one of skill in the art in possession of a representative number of molecules

having the varied attributes and features of species within the claimed genus. Accordingly, it is maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO:11. The rejection is therefore maintained.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634

~~1/8/07~~
1/16/07